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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,467	10/23/2001	Lilia Shapiro	9124.103USC1	6551

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EXAMINER

ISABELLA, DAVID J

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 04/09/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,467

Applicant(s)

SHAPIRO ET AL.

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-14,39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,7-14,39 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Specification

The disclosure is objected to because of the following informalities: pages 51-53 of the specification sets forth a list of references. If applicant wishes to have references included in the consideration as prior art, then the references should be properly listed on the PTO 1449. If these references are not directly incorporated into the body of the specification then the references should be deleted.

Appropriate correction is required.

Status of the Claims

Claims 1,2,7-14,39 and 40 are currently pending for action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an artificial organ, does not reasonably provide enablement for cultured cells that are fully active and equivalent to the active cells of the organ. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,2,7-14,39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite. Pores do not have wall thickness.

Claim 2 is an improper Markush format. "Comprising" should be changed to consisting. There is no antecedent support for "the polyanionic polysaccharides"; and "the polycationic polysaccharide".

Claims 7-13 are indefinite. These claims are directed to elements used in the process for producing the polysaccharide sponge. These elements as set forth are not positively incorporated as comprising the sponge. Claims 7,8 are directed to a group of cross-linking agents that are used as an agents to form the final product. It is not clear from the claim if the agent is a part of the final product or an intermediate element used to obtain a final product. Claim 9, there is no support for "said cross-linker".

Additionally, it is not clear from claim 9 if the cross-linker is a part of the final product or an agent used in an intermediate step to obtain the final product.

Claim 10, it is not clear what is being claimed. It is not clear how this dependent claim further defines the polysaccharide sponge of claim 1. There is no nexus between the sponge and the polysaccharide solution. It is not clear what comprises the "solution" as claimed.

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Claim 11 fails to positively set forth the composition of the sponge. The claim is directed to elements used in the intermediate steps to obtain the final product. It is not clear what comprises LF 120 and HVCR alginates. The use of Trademarks in the claims is not proper.

Claims 12 and 13, see rejection to claim 11 supra.

Claim 14, it is not clear what applicant intends for the scope of the claim. Clearly, the functional recitation for use as a matrix, substrate or scaffold fails to impart further structural distinction to claim 1. The claim should be reworded in Markush format.

Claim 39 is indefinite. There is no antecedent support for "representative cells", "the stage". It is not clear from the specification how one determines if the cells are fully active and equivalent to the active cells of the organ.

Claim 40, see rejection to claim 39 supra.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,7-14,39 and 40 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bell, et al.

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Bell, et al discloses a polysaccharide foam/sponge used in tissue repair and reconstruction. The foam is porous with the pores having openings and wall thickness falling within the range as claimed. See column 2, lines 33+. Bell, et al fails to specifically disclose the modulus of the foam but utilizes the foam for in vivo applications identical to applicant. Examiner contends that since the foam is used in a similar manner as applicant's polysaccharide sponge, the modulus of the foam of Bell, et al would inherently fall within the broad range as claimed by applicant. The foam of Bell, et al may be used as glandular implants that is seeded with appropriate glandular cells including hepatocytes (See column 4, lines 52+).

With respect to claims 7-13, in so far as the claims are definite and define the polysaccharide sponge, Bell, et al uses cross-link agents to polymerize the biopolymer to form the foam.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3579 for regular communications and 703-305-3580 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



DAVID J. ISABELLA
Primary Examiner
Art Unit 3738

dji
April 4, 2003